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Moderators, mediators, and nonspecific predictors of outcome after cognitive rehabilitation of executive functions in a randomized controlled trial

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Abstract

Moderators, mediators, and nonspecific predictors of treatment after cognitive rehabilitation of executive functions in a randomized controlled trial

Objective: To explore moderators, mediators, and nonspecific predictors of executive functioning after cognitive rehabilitation in a randomized controlled trial, comparing Goal Management Training (GMT) with an active psycho-educative control-intervention, in patients with chronic acquired brain injury.

Methods: Seventy patients with executive dysfunction were randomly allocated to GMT (n=33) or control (n=37). Outcome measures were established by factor-analysis and included cognitive executive complaints, emotional dysregulation, and psychological distress.

Results: Higher age and IQ emerged as nonspecific predictors. Verbal memory and planning ability at baseline moderated cognitive executive complaints, while planning ability at six month follow-up mediated all three outcome measures. Inhibitory cognitive control emerged as a unique GMT specific mediator. A general pattern regardless of intervention was identified; higher levels of self-reported cognitive-, executive-, symptoms of emotional dysregulation-, and psychological distress at six month follow-up mediated less improvement across outcome factors.

Conclusions: The majority of treatment effects were nonspecific to intervention, probably underscoring the variables' general contribution to outcome of cognitive rehabilitation interventions. Interventions targeting specific cognitive domains, such as attention or working memory, need to take into account the patients' overall cognitive and emotional self-perceived functioning. Future studies should

investigate the identified predictors further, and also consider other predictor candidates.

Keywords: Executive function, Goal Management Training, Cognitive rehabilitation, Randomized controlled trial, Predictors of outcome

Introduction

Executive functioning (EF) is an umbrella-term capturing a number of processes promoting control and regulation of cognition, emotion, and behavior (Cicerone et al., 2006; Stuss, 2011), and is required for self-directed purposive behavior (Lezak, Howieson, & Bigler, 2012).

In daily life, executive dysfunction often manifests as problems with adapting and responding appropriately to the environment, as well as with the formulation of goals, planning, initiation and regulation of behavior (Cicerone & Giacino, 1992; Robertson & Levine, 2013). Dysexecutive problems frequently result from acquired brain injury (ABI), and are associated with inefficient self-management (Lewis, Babbage & Leathem, 2011), reduced independence and productivity (Hanks, Rapport, Millis & Deshpande, 1999), and negative psychosocial and vocational outcomes (Draper & Ponsford, 2008; Flemming, Tooth, Hassell & Chan, 1999). Studies have also shown significant associations between executive dysfunction and psychiatric symptoms following ABI (Aldao, Nolen-Hoeksema & Schweizer, 2006; Zgaljardic et al., 2015), with depressive symptoms being the most common after both traumatic brain injury (TBI) (Hart et al., 2012) and stroke (Ayerbe, Ayis, Wolfe & Rudd, 2013).

Metacognitive strategy training, including training of self-monitoring and self-regulation, is recommended as practice standard for executive dysfunction after TBI (Cicerone et al., 2011; Kennedy et al., 2008). Goal Management Training (GMT) is a structured, interactive, and manual-based rehabilitation protocol for executive deficits (Levine et al, 2000; Robertson, 1996). The main objective of GMT is to learn to regularly interrupt ongoing behavior in order to reflect on current behavior and intentions ("stop-and-think"), and monitor performance (Levine et al., 2011). The intervention involves learning and practicing a self-instruction algorithm; stop behavior,

state the current goal, compare ongoing behavior and goal, and adjust if necessary. The role of sustained attention is emphasized to actively maintain goals in working memory, and reinforced through mindfulness exercises (Kabat-Zinn, 1990).

Studies of patients with ABI have reported GMT-associated improvements of performance on tasks demanding executive and sustained attention (Levine et al., 2000; 2011; Schweizer et al., 2008), and self-reported executive functioning in daily life activities (Levine et al, 2000; Grant, Ponsford & Bennett, 2012). Several studies suggest that GMT combined with other interventions (e.g. multifaceted approaches) might increase its effectiveness in ameliorating executive problems in everyday life (Bertens et al., 2015; Metzler-Baddeley et al., 2010; Miotto et al., 2009; Novakovic-Agopian et al., 2011; Spikman et al., 2010).

However, it is challenging to adapt findings from group-based randomized controlled trials (RCTs) to clinical decisions at the individual patient level. There is generally sparse knowledge about which specific interventions and intervention components work best for whom, when in the course of recovery, and under what conditions. There is also a need for more knowledge about the specific patient characteristics that moderate the effect of treatments targeting executive functioning in order to guide individualized clinical decision-making.

In a metacognitive intervention that included GMT, Spikman et al. (2013) reported that pre-treatment deficits in emotion recognition, a crucial aspect of social cognition, negatively affected the learning of compensatory strategies for executive dysfunction. However, pre-treatment executive dysfunction assessed by neuropsychological tests did not. Studies have suggested GMT to be better suited for less cognitively impaired patients (Krasny-Pacini et al., 2013).

To the authors' knowledge, only one study (Bertens, Fasotti, Boelen & Kessels, 2016) has explored predictors of outcome after GMT. To distinguish between the predictors; e.g. moderators, mediators, and nonspecific predictors, Bertens et al. (2016) applied the guidelines outlined by Kraemer, Wilson, Fairburn and Agras (2002). In line with this, a baseline patient characteristic that interacts with treatment(s) and affects outcome is defined as a moderator, e.g. did age at onset of intervention moderate (predict) outcome? A mediator on the other hand, is a post-treatment variable that correlates with treatment(s) and influences outcome. For example, given that attention training was addressed by the intervention, did improved attention scores post-training mediate (predict) outcome? A nonspecific predictor is a variable that neither interacts nor correlates with treatment at baseline or post-treatment, but predicts outcome.

Bertens and colleagues´ (2016) exploratory study compared standard GMT and "errorless GMT", the latter referring to a highly structured approach to prevent the errors that commonly occur during task learning. They reported two significant moderators; higher age was associated with better everyday task performance after conventional GMT, and higher IQ was associated with better performance after errorless GMT. Higher executive function scores after training, measured on a composite score based on seven neuropsychological tests, predicted improved everyday task performance across both interventions, e.g. mediated treatment outcome.

We conducted a RCT investigating the efficacy of GMT as a group-based cognitive rehabilitation intervention for executive dysfunction following ABI. A new module for emotional regulation as well as external cuing, were included in the intervention. When compared to an active control condition, a psycho-educative intervention (the Brain Health Workshop), favorable effects of GMT on cognitive aspects of EF, including executive attention, and emotional regulation skills were

observed. The strongest effects were seen at six month follow-up, possibly reflecting that the strategies learned were consolidated and applied in everyday life. (Tornås et al., 2016a; Tornås et al., 2016b).

Thus, the aim of the present study was to examine potential moderators, mediators, and nonspecific predictors of cognitive aspects of EF and emotional regulation, at six month follow-up. Psychological distress was also included as outcome variable, as premorbid psychiatric symptoms are reported to strongly affect executive functioning in daily life in patients with mild TBI (Donders & Strong, 2016). Given the limited research literature, the choice of predictors was guided by Bertens et al´s. paper (Bertens et al., 2016). Candidate moderators included medical and demographic characteristics (age, sex, time since injury, type and localization of injury, and IQ), baseline neuropsychological test performance (attention, memory, and planning ability), baseline self-reported cognitive function, executive function, emotional regulation, and psychological distress. Six month follow-up scores of neuropsychological test performance (attention and planning ability), self-reported cognitive and executive function, emotional regulation, and psychological distress were entered as potential mediators.

Methods

Procedure

The study was carried out at Sunnaas Rehabilitation Hospital (Norway) and has previously been described in detail (see Tornås et al., 2016a). It was conducted in accordance with the Helsinki Declaration, approved by the Regional Committee for Medical Research Ethics (2012/1436), South-Eastern Norway, and all participants provided written informed consent.

A total of 178 former patients were invited to participate through an information letter. Ninety gave written informed consent, and subsequently underwent a screening interview. The eligibility criteria were as follows: having a documented, non-progressive ABI, be at least 6 month post-injury, experience ongoing executive dysfunction documented either by self-report or neuropsychological assessment, and be between 18 and 67 years old. Neurodegenerative disorders, severe cognitive impairments precluding participation in the program, major psychiatric diseases, and/or ongoing substance abuse were set as exclusion criteria. Six patients did not meet the inclusion criteria, and fourteen declined participation due to practical reasons (e.g. scheduling difficulties), resulting in a final sample of 70 participants.

After randomization, 33 participants were allocated to GMT, and 37 to the Brain Health Workshop (BHW) (figure 1). Assessments were conducted at baseline (T1), immediately after the end of training (T2), and at six-month follow-up (T3). All assessors were blind to group allocation at all times. The participants were informed that the study investigated two different approaches to brain training (Figure 1).

[INSERT FIGURE 1 HERE]

Interventions

The GMT and the BHW protocols were based on Levine et al´s (2011) research protocol, and translated to Norwegian. Both interventions consisted of eight modules of 2 hours each, and were administered in groups consisting of 5 to 7 participants. The eight modules were divided over four days. The groups met for one day every other week, having one module before lunch and one after. None of the groups ever met each other. The protocols have been described in detail elsewhere (Stubberud, Langenbahn, Levine, Stanghelle & Schanke, 2013; Tornås et al., 2016a; 2016b). In summary, the original nine GMT modules were compressed into seven modules, and a newly

developed module for emotional regulation was added. The GMT protocol consisted of the following eight modules: Present and absent mindedness (1), Slip-ups in daily life (2), The automatic pilot and the mental blackboard (3), State your goal (4), Making decisions (5), Splitting tasks into sub-tasks (6), Emotional regulation (7), and Check and summary (8). The new module for emotional regulation introduced core concepts from Cognitive Behavioral Therapy, and emphasized the mutual relationship between thoughts, situations and emotions (Beck, 2009), and how negative self-talk can become "automatic" and interfere with goal-achievement. Negative self-talk and feelings were discussed as internal "alarm-signals" to "STOP", and to apply mindfulness-exercises in order to enhance awareness of the ongoing situation and goals. Examples from daily-life were used in order to facilitate an increased understanding of the concepts.

BHW comprised educational materials and various lifestyle interventions that are typically part of psycho-educative brain rehabilitation programs (Becker, Kirmess, Tornas, & Løvstad, 2014). Key topics addressed brain function and dysfunction, brain plasticity, memory, EF, and attention. Particular attention was given to stress, physical exercise, sleep, nutrition, and energy management. Homework and within-session activities included reading assignments, brain-games and puzzles, testing of acquired knowledge, and practical exercises like keeping a sleep log (Table 1). GMT and BHW were carefully matched regarding amount of training, educational material, therapist contact, and homework. As combining external cuing with GMT has been reported to improve task performance (Manly, Hawkins, Evans, Woldt & Robertson, 2002) and enhance goal management (Fish et al., 2007), all participants received a daily text-message stating "STOP" after the fourth module, amounting to 28 per participant.

[INSERT TABLE 1 HERE]

Moderators, mediators, and nonspecific predictors

Due to the very limited number of studies regarding predictors in GMT, a hypothesis-generating approach with exploratory analysis was chosen, with comparable variables as those used by Bertens et al. (2016) selected as potential predictors. The guidelines outlined by Kraemer, Wilson, Fairburn and Agras (2002) were applied to differentiate between moderators, mediators, and nonspecific predictors. A baseline patient characteristic that interacts with treatment(s) and affects outcome was defined as a moderator, e.g. moderators specify for whom or under what conditions the treatment works. Thus, candidate demographic and medical moderators included the following baseline variables; age, sex, time since injury, as well as etiology and localization of brain injury. Candidate neuropsychological assessment moderators included baseline measures of general intellectual capacity (total T score on the Wechsler Abbreviated Scale of Intelligence, WASI; Wechsler, 1999), raw-scores for delayed verbal recall (California Verbal Learning Test - II, Standard Form, CVLT-II; Delis, Kaplan & Kramer, 2000), and measures of strategic spatial planning (the Tower test; Delis et al., 2001). Measures of attention covered inhibition (raw-scores commission errors; Conners' Continuous Performance Test II, CPT-II; Conners, 2000; total time to complete the Color-Word Interference Test 3, CWIT3; Delis et al., 2001), sustained attention (raw-scores omission errors; CPT-II), and shifting (total time Color-Word Interference Test 4, CWIT4; Delis et al., 2001).

Candidate self-reported daily life EF moderators included baseline measures of the Behavior Rating Inventory of Executive Function-Adult version (BRIEF-A; Gioia et al., 2000), and the Dysexecutive Questionnaire (DEX; Burgess, Alderman, Wilson, Evans & Emslie, 1996), cognitive functioning with the Cognitive Failures Questionnaire (CFQ; Broadbent, FitzGerald & Parkes, 1982), emotional regulation with

The Brain Injury Rehabilitation Trust Regulation of Emotions Questionnaire (BREQ; Cattran, Oddy & Wood., 2011), and psychological distress with the Hopkins Symptom Checklist-25 (HSCL-25; Derogatis, Lipman Rickels, Uhlenhuth & Covi, 1974).

A mediator was defined as a post-treatment variable that correlates with treatment(s) and influences outcome, e.g. either as a main effect of treatment(s) or an interaction effect for a particular treatment (Kraemer, Wilson, Fairburn, & Agras, 2002). A mediator thus identifies possible mechanisms through which a treatment might achieve its effect. In line with this definition, candidate mediators of cognitive and executive functioning addressed by GMT included six month follow-up scores of neuropsychological measures for attention (CPT-II, CWIT3, and CWIT4), and strategic planning (the Tower test). Similarly, candidate mediators of daily life functioning addressed by GMT included self-reported cognitive functioning (CFQ), executive functioning (BRIEF-A and DEX), emotional regulation (BREQ), and psychological distress (HSCL-25).

Finally, a variable that neither interacts nor correlates with treatment at baseline or post-treatment, but predicts outcome, is defined as a nonspecific predictor (Kraemer et al., 2002).

Treatment outcome measures

There is no gold standard measure that covers all relevant outcomes after treatment of executive dysfunction (Chan et al., 2008). To take into account the multiple aspects of executive functioning, and avoid type 1 errors due to numerous comparisons, composite outcome measures were established by the application of factor analysis of the six month follow-up subscale scores of the following measures: BRIEF-A, DEX, and the total score from the BREQ. These measures were chosen because they assess significant aspects of executive functioning in daily life. Furthermore, previous reports from this

RCT study have indicated GMT-related effects on these measures of cognitive executive functioning (Tornås et al., 2016a), and emotional regulation (Tornås et al., 2016b). In addition, the subscales for depression and anxiety from HSCL-25 were added to the factor-analysis, to examine possible overlap between emotion regulation and psychological distress. Notably, Donders and Strong (2016) reporting that high elevations on the BRIEF-A were strongly affected by premorbid psychiatric complications in patients with mild TBI.

The examination of eigenvalues and scree plots suggested retaining three factors (Table 2). After oblimin rotation with Kaiser Normalization, six subscales from the included questionnaires loaded on the first factor which comprised the emotional dysregulation factor, five subscales loaded on the second factor, representing measures of cognitive executive complaints, and the third factor reflected only psychological distress. The subscale scores included in each factor were summarized to a total T-score for each of the three factors, where a low total-score indicates less, and a high score represents more symptoms. Of interest, the loadings of the subscales from the BRIEF-A paralleled previous studies on the factor structure of BRIEF-A (Donders & Strong, 2016; Roth, Lance, Isquith, Fischer, & Giancola, 2013), with the exception of the subscale Shift.

To avoid conceptual circularity, subscales included in the outcome factor in question were not explored as potential predictors of that particular factor. For example, baseline and six month follow-up scores for BRIEF-A, DEX, and BREQ were not analyzed as candidate predictors of the emotional regulation factor.

[INSERT TABLE 2 HERE]

Statistical analysis

In line with Bertens et al. (2016), candidate predictor variables (moderators, mediators, and nonspecific predictors) were examined using univariate general linear model analyses. The three outcome measures (factors) were in turn entered as the dependent variable, with baseline values of the outcome factor entered as a covariate, and the possible predictor (grand mean centered), and predictor-by-treatment group interaction entered as independent variables. Treatment group (GMT or BHW) was entered as a fixed factor. Post hoc general linear models were used to investigate the nature of significant predictors or interaction terms (Kraemer et al., 2002). Analyses used the intention-to-treat principle, including all randomized subjects, regardless of whether they completed treatment. Three participants dropped out after completing the first two modules; two participants in the GMT group (personal reasons/pregnancy), and one participant in the BHW group (personal reasons).

In accordance with Kraemer et al. (2002), the baseline variables (including demographic information) were classified as nonspecific predictors in case of a significant main effect on outcome, and as a moderator in case of a significant interaction effect between the variable and the treatment(s). Six month follow-up variables that significantly correlated with treatment(s) were classified as potential mediators, if a main effect or an interaction effect for a particular treatment was significant.

The strength of experimental effects was interpreted with effect size statistics, including partial eta-squared (η_p^2) for ANOVA results and eta-squared (η^2) for *t*-tests. An effect size of .01 was considered small, .06 considered medium, and .14 considered large (Cohen, 1988). Analyses were conducted using IBM SPSS statistics 21.0.

Results

The groups did not deviate from each other at baseline with regard to demographic or medical variables, nor on self-reported symptoms, and they performed comparably on neuropsychological measures. Mean age was 42.9 years (*SD* 13.0), a slight majority were male (38/54%), mean length of education was 13.4 years (*SD* 2.4), and the majority were in the chronic phase of their brain injury, with a mean of 8.1 years (*SD* 9.4) since injury. Traumatic brain injury was the dominant etiology (45/64%). Nineteen (27%) were employed or students, and 44 (63%) were either living with a partner or were in a relationship. Structural magnetic resonance imaging (MRI) scans at baseline showed that the frontal lobes were the most frequent cortical location of damage (25/36%), followed by the temporal (14/20%), and parietal lobes (10/14%). For more detailed sample descriptions, see Tornås et al. (2016a; 2016b).

To ease reading of results, findings regarding moderators and nonspecific predictors (baseline variables) in relation to all three outcome measures will first be presented for background and demographic variables, neuropsychological variables, and self-reported questionnaires, respectively. Then, the results for mediators and nonspecific predictors (six month follow-up variables) of the three outcome measures are presented for neuropsychological variables and self-reported questionnaires.

Moderators and nonspecific predictors (baseline)

Table 3 shows the status of the demographic and *baseline* variables as candidate moderators of the outcome measures cognitive executive complaints, emotional dysregulation, and psychological distress at six month follow-up, in terms of a main effect with or without an interaction with treatment effect.

Background and demographic moderators and nonspecific predictors

No background or demographic variables were identified as moderators. IQ emerged as a nonspecific predictor of cognitive executive complaints, in that higher IQ at baseline predicted more complaints post-training (B = .63; $t_{1,65}$ = 2.15; P<.036). Age appeared as a nonspecific predictor of psychological distress, as higher age predicted lower levels of psychological distress post-training (B = -.211; $t_{1,66}$ = -2.214; P<.03).

Neuropsychological test performance moderators and nonspecific predictors

Verbal memory (delayed recall; CVLT-II) was identified as a moderator of cognitive executive complaints. Post-hoc analyses indicated that better baseline memory-scores in the GMT group predicted higher levels of cognitive executive complaints post-training ($F_{1,31}$=8.72; P<.006; B = 6.27; $t_{1,31}$ = 2.95; P<.006). Higher scores on verbal recall emerged as a nonspecific predictor of psychological distress, irrespective of group (B = .13; $t_{1,66}$ = .39; P<.7).

Strategic planning (total number of moves on the Tower test) was identified as a moderator of cognitive executive complaints in the control group. Post-hoc analyses indicated that more moves to complete the test at baseline predicted higher levels of cognitive executive complaints post-training ($F_{1,34}$=6.38; P<.017; B = .51; $t_{1,34}$ = 2.53; P<.017). Regardless of group, the total number of moves was also identified as a non-specific predictor of self-reported emotional dysregulation and psychological distress, as poorer scores at baseline predicted higher levels of both emotional dysregulation (B = .65; $t_{1,65}$ = 2.61; P<.011) and psychological distress (B = .1; $t_{1,66}$ = 2.41; P<.019).

Self-reported moderators and nonspecific predictors

None of the self-reported measures emerged as moderators of any of the three outcome measures, but a number of nonspecific predictors were identified.

Self-reported cognitive failures (CFQ; B = 1.75; $t_{1,65}$ = 3.13; P<.003), emotional dysregulation (BREQ; B = 1.48; $t_{1,64}$ = 2.53; P<.014), and psychological distress (HSCL-25; B = 2.09; $t_{1,64}$ = 3.26; P<.002), all emerged as nonspecific predictors of cognitive executive complaints.

Following a similar pattern, self-reported cognitive failures (CFQ) (B = 2.18; $t_{1,63}$ = 3.28; P<.002), and psychological distress (HSCL-25) (B = 1.8; $t_{1,64}$ = 2.34; P<.023), were identified as nonspecific predictors of emotional dysregulation.

Furthermore, self-reported cognitive failures (CFQ; B = .36; $t_{1,64}$ = 3.14; P<.003), executive function (BRIEF-A; B = .57; $t_{1,65}$ = 3.77; P<.0001), executive dysfunction (DEX; B = .52; $t_{1,65}$ = 5.12; P<.0001), and emotional dysregulation (BREQ; B = .36; $t_{1,65}$ = 3.53; P<.001), emerged as nonspecific predictors of psychological distress.

[INSERT TABLE 3 HERE]

Mediators and nonspecific predictors (six month follow-up)

Table 4 shows the status of neuropsychological and self-report variables at the six month follow-up (*post-training*) as candidate mediators of cognitive executive complaints, emotional dysregulation, and psychological distress, either mediating treatment in general (main effect) or a specific treatment (interaction effect).

Neuropsychological mediators and nonspecific predictors

Strategic planning (the total achievement score on the Tower-test) was identified as a mediator of cognitive executive complaints in the control group, due to an interaction effect. Better planning scores mediated lower levels of cognitive executive complaints ($F_{1,33}$=5.38; P<.027; B = -3.09; $t_{1,33}$ =-2.32; P<.027).

Strategic planning (the total achievement score on the Tower-test) also mediated emotional dysregulation in both groups, due to interaction effects. Post hoc analysis indicated that GMT participants with better planning sum-score ($F_{1,31}$=5.6; P< .025; B = 2.78; $t_{1,31}$ = 2.37; P<.025) reported higher levels of emotional dysregulation, while the opposite pattern was evident in the control group ($F_{1,33}$=7.27; P<.011; B = -4.51; $t_{1,33}$= -2.7; P<.011).

Furthermore, strategic planning performance mediated psychological distress in both groups, reflected in a main effect. Lower planning scores (B = .062; $t_{1,65}$=2.626; P<.011) mediated higher levels of psychological distress.

Inhibitory control of attention (time to complete the CWIT3) was identified as a mediator of psychological distress in the GMT group, due to an interaction effect. Better inhibition scores ($F_{1,30}$=8.68; P<.007; B = .141; $t_{1,30}$=2.946; P<.007) mediated lower levels of psychological distress.

Self-reported mediators and nonspecific predictors

Self-reported cognitive failures (CFQ), emotional dysregulation (BREQ), and psychological distress (HSCL-25) mediated cognitive executive complaints. Higher levels of cognitive failures (B = 1.49; $t_{1,64}$ = 6.12; P<.0001), emotional dysregulation (B = 1.07; $t_{1,64}$ = 4.18; P<.0001), and psychological distress (B = .94; $t_{1,64}$ = 4.66; P<.0001), mediated levels of cognitive executive complaints.

Cognitive failures (CFQ) also mediated emotional dysregulation, as higher levels of cognitive failures mediated higher levels of emotional dysregulation (B = 1.137; $t_{1,64}$= 5.95; P<.0001). Psychological distress (HSCL-25) was identified as a mediator of emotional dysregulation in the control group, due to an interaction effect. Higher levels of psychological distress mediated higher levels of emotional dysregulation ($F_{1,33}$=31.27; P< .0001; B = 1.85; $t_{1,33}$ = 5.59; P<.0001).

Cognitive failures (CFQ) and executive dysfunction (DEX) mediated psychological distress in the control group, due to an interaction effect. Higher levels of self-reported cognitive failures ($F_{1,34}$=42.5; P< .0001; B = .4; $t_{1,34}$=6.52; P<.0001) and executive dysfunction ($F_{1,33}$=65.9; P<.0001; B = .51; $t_{1,33}$=8.12; P<.0001), mediated higher levels of psychological distress. Executive functioning in daily life (BRIEF-A) and emotional regulation (BREQ) mediated psychological distress across treatment groups, as more self-reported executive problems (B =.45; $t_{1,64}$=5.77; P<.0001) and emotional dysregulation (B = .32; $t_{1,65}$=5.75 P<.0001) mediated higher levels of psychological distress.

[INSERT TABLE 4 HERE]

Discussion

The main aim of the present study was to explore potential moderators, mediators, and nonspecific predictors of executive functioning in daily life following cognitive rehabilitation, in a RCT comparing a metacognitive intervention (GMT) and a psycho-educational intervention (BHW) in patients with chronic ABI. In this robust design, common effects of cognitive rehabilitation were expected to be captured in main effects, while interactions involving group could potentially identify treatment-specific effects. It is reasonable to assume that non-specific treatment effects will be at play in cognitive rehabilitation, as in many other psychological interventions (Chorpita et al., 2011).

The majority of treatment effects were not specific to group, probably reflecting the variables' contribution to cognitive rehabilitation interventions at a general level. Higher IQ and higher age were non-specific predictors of outcome, while verbal memory and planning ability moderated outcome, although in unexpected directions.

Self-reported cognitive, executive, emotional, and psychological functioning mediated outcomes post-training. Of particular interest were the findings that cognitive

failures in everyday life not only mediated cognitive executive complaints, but also emotional and psychological functioning. In a similar way, higher levels of emotional dysregulation mediated more psychological distress. One unique GMT contribution emerged, in that improved inhibitory control of attention after training mediated less psychological distress.

Moderators and nonspecific predictors at baseline

Better verbal memory at baseline predicted higher levels of cognitive executive complaints post-training in the GMT-group, and emerged as a nonspecific predictor of psychological distress for both groups. These results were unexpected, given studies suggesting metacognitive interventions to be better suited for less cognitively impaired patients (Krasny-Pacini et al., 2013). However, good long-term recall might imply better memory for cognitive failures, and as such contribute to more psychological distress. Comparably, higher IQ was associated with more cognitive executive complaints, potentially reflecting that better cognitive abilities are associated with increased awareness of deficits after brain injury (Ownsworth, McFarland & Young, 2009). Still, there is a need to better understand how cognitive and executive test performance relates to everyday functioning (Cicerone et al., 2006), and training effects.

Strategic planning, the ability to identify and organize the steps needed to carry out an intention or reach a goal (Lezak, 1995), constitutes an important aspect of executive functioning (Chan, Shum, Toulopoulu & Chen, 2008; Stuss, 2011). Thus, the findings that lower planning scores at baseline moderated higher levels of cognitive executive complaints (the BHW-group), and in general, predicted higher levels of emotional dysregulation and psychological distress, were not surprising. Ownsworth and Fleming (2005) claimed that strategic behavior like planning is of great importance for emotional and psychological functioning, because deficient strategic behavior leads

to less positive expectations regarding the future, due to a decrease in patients' self-efficacy beliefs (Cicerone, 2012).

Higher age was associated with lower levels of psychological distress in both groups, which is in line with reports that young individuals with TBI tend to experience increased psychological distress over time (Senathi-Raja, Ponsford and Schönberger, 2010). Of note, other studies combining GMT with psycho-education (van Hoorens et al., 2007), or memory- and psychosocial training (Stuss et al., 2007; Winocur et al., 2007), have reported beneficial results for healthy elderly. In a systematic review on interventions for executive functions, Kennedy et al. (2008) concluded that the evidence was insufficient to make clinical recommendations for older adults. Thus, while this study suggests an advantage of higher age to psychological outcome, the role of age related to outcome after metacognitive interventions, remains unclear.

Impaired self-reported cognitive, executive and emotional functioning emerged as nonspecific predictors of higher levels of difficulties on all three outcome measures, across both interventions. This could indicate that higher overall symptom-load reflects a more chronic condition, or is more resistant to change.

Mediators and nonspecific predictors at six month follow-up

Better planning performance at follow-up mediated lower levels of cognitive executive complaints in the control-group, thus identifying improved planning as a possible mechanism through which the psycho-educative intervention achieved its effect. However, planning was not specifically addressed or trained in the control condition. The finding could therefore reflect test-retest effects of the test measures, or nonspecific treatment effects, as reported in other studies applying variants of tower tests (Lemay, Bedard, Rouleau, & Tremblay, 2004; Spikman et al., 2010).

Surprisingly, planning abilities – a key component of GMT, mediated higher levels of emotional dysregulation in the GMT-group, and lower levels in the control group. The pattern of findings related to the Tower test are difficult to interpret, and in need of replication. One option might be that better planning abilities could also be related to better insight, leading to greater frustration with difficulties that impact on regulation of emotions.

Better inhibitory control (CWIT3) was associated with lower levels of psychological distress in the GMT-group. The other inhibitory control measure (CPT-II, Commission errors) approached significance in the same direction, while measures for sustained attention (CPT-II, Omission errors) and shifting (CWIT4) showed no effects. Impaired inhibitory control has been suggested as a possible predictor of depression relapse in major depressive disorder (Schmid & Hammar, 2013), and a favorable effect of GMT on inhibition has been reported in previous studies (e.g. Levine et al, 2011; Stubberud et al., 2013). Changes in inhibitory attention control, an important aspect of executive function (Robertson & Garavan, 2000), might thus be a possible mechanism mediating success in GMT. The executive attention network is suggested to be involved in the self-regulation of both affect and cognition (van der Horn, Liemburg, Aleman, Spikman & Naalt, 2016). Attention could thus underlie voluntary control of both thoughts and feelings (Posner & Rothbart, 2007), with the inhibitory aspect of attention control playing an important role. Of note, the current version of GMT specifically addressed emotional functioning, possibly strengthening this link between attentional control and emotion.

A general pattern was evident irrespective of group; more self-reported symptoms at 6 month follow-up mediated higher symptom levels in all three outcome measures. However, there were three group-specific findings related to the control

group in that higher levels of psychological distress mediated treatment effects related to emotional dysregulation, and more cognitive failures and self-reported executive deficits mediated treatment effect related to psychological distress. Lack of functional and cognitive recovery in TBI patients have been associated with worsening of mood over time, regardless of depression level after the first year (Hart et al., 2012). Thus, these results could reflect the continuation of cognitive and executive symptoms, despite the effort to improve by participating in the psycho-educational intervention. The finding that poor planning performance emerged as a mediator of higher levels of psychological distress in both groups could also support this hypothesis.

Goal Management Training specific findings

The only pre-existing GMT study exploring predictors of treatment effects is that of Bertens et al. (2016), where two variants of GMT were compared, leaving it difficult to identify the unique contributions of GMT. In comparing GMT and a psycho-educative intervention, the current study had a higher potential to identify GMT-specific contributions. The interaction effects involving GMT were related to good verbal memory which was associated with more cognitive executive complaints. Secondly, better planning scores mediated higher levels of emotional dysregulation, and finally, better inhibitory attentional control mediated lower levels of psychological distress. As discussed, the first two results were unexpected and the implications remain unclear.

The finding that better scores for inhibitory control mediated treatment outcome in the GMT group only, indicates that improved inhibitory control is a result unique to GMT. This interpretation is in line with the theoretical assumptions underlying GMT, as an intervention aiming to enhance attentional control, with inhibition considered a central element (Robertson & Garavan, 2000; Levine et al., 2011). It is also in accordance with several studies finding that attentional control is improved by GMT

(Levine et al, 2011; Stubberud et al., 2013).

Strengths and limitations

The study had a strong design, as it was carried out as a RCT, included an active control-group, had blinded assessors at all assessment-points, and had a large study sample relative to earlier studies. Thus, the study countered many of the methodological challenges of previous metacognitive interventions. Still, some limitations should be noted. The inclusion of external cuing and the new module for emotional regulation in the GMT protocol hampers identification of the unique contributions of each component to treatment effects. Despite having a large study sample relative to earlier studies, it was relatively modest for applying predictor analyses, and also included a large number of variables. Given the limited literature in the field, the choice of candidate predictors was exploratory, lacking specific a priori hypotheses regarding moderators and mediators. Thus, the role and implication of certain background (age, IQ) and neuropsychological variables (memory and planning) regarding outcome need further exploration and replication.

Although the composite outcome measures had internally high and distinct factor-loadings, their psychometric properties are not well known, and they were not totally independent of the candidate predictors. Future studies should be planned with an independent outcome measure embedded in the design, although this on the other hand poses obstacles with lack of baseline values. Capturing problems of executive functioning in formal assessments constitutes a methodological challenge in all treatment studies (Cicerone et al., 2006).

Finally, the reliance on self-report measures is a limitation. Factors such as reduced insight and cognitive impairments (Cantor et al., 2014; Prigatano & Altman, 1990), demand characteristics (McCambridge, de Bruin, & Witton, 2012), and social

desirability bias (Logan, Claar, & Scharff, 2008) may have affected the validity of the self-report.

Conclusions and clinical implications

The present study explored possible predictors of executive functioning in daily life after cognitive rehabilitation, comparing GMT and a psycho-educative intervention. The majority of treatment effects were not specific to group, probably reflecting the variables' contribution to cognitive rehabilitation interventions at a more general level. Thus, even when the aim is to improve specific cognitive functions like attention or working memory, the more general predictors of outcome, such as emotional functioning, need to be taken into account. Clinically speaking, treatment of specific deficits needs to be targeted within a broader context, taking the patients' cognitive executive, emotional, and psychological functioning as well as their self-understanding into consideration. This finding is important to the rehabilitation field, as little work has been done regarding detection of general and specific factors affecting treatment outcome, not only with regard to GMT, but cognitive rehabilitation in general. Patients' increased confidence in symptom management after metacognitive interventions targeting self-regulation, is suggested to be an important factor underlying generalization of treatment effects to psychological functioning and quality of life (Cicerone, 2012), similar to the results of this study. It is therefore suggested that future studies include self-efficacy as a potential predictor, possibly operating both as a moderator and mediator, of cognitive, emotional, and psychological functioning in the chronic phase after ABI.

Future studies should also include more candidate predictors; a wider range of neuropsychological assessment of EF and information from significant others, in larger patient samples and with robust outcome measures. Of particular interest was the unique

GMT related outcome linking improved inhibitory control at six month follow-up and less psychological distress. This possibly highlights the close interdependency between basic cognitive executive processes and psychological functioning, and should be explored further.

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Table(s) with caption(s) (on individual pages)

Figure caption(s) (as a list)

Table 1**.** Description of the modules and objectives in Goal Management Training and Brain Health Workshop

Training day		**Goal Management Training session/Objectives**	**Exercises within-session**	**Brain Health Workshop session/Objectives**	**Exercises within-session**
1	Morning session	*1. Present and absent mindedness*: Introduction, Goals in daily life, Present- and absent- mindedness	Clapping task Present-mindedness 1	*1. Introduction:* Introduction, Brain anatomy and cognition, Etiology of brain damage	Visual perception
	Afternoon session	*2. Slip-ups:* Absentmindedness and slip-ups, Awareness of probability of slip-ups, Present-mindedness	Clapping task Present-mindedness 2 Body scan task	*2. Neuroplasticity:* Brain damage and assessment, Functional assessment of brain activity, Brain plasticity	Mental training
	Home-work	Record daily slips. Practice daily present-mindedness and present-mindedness 2. Do the Body scan task.		Reading assignments: Acquired brain injury and neuroplasticity. Do Brain puzzles.	
2	Morning session	3. *Stop the Automatic Pilot/The Mental Blackboard:* The automatic pilot and errors, The mental blackboard (working memory), "STOP!" to check the mental blackboard	Card dealing Clapping task with "STOP!" Present mindedness 3 (breath focus)	*3. Memory I:* Review, The importance of memory, Types of memory, Memory processes	Brain jeopardy
	Afternoon session	*4. State your goal:* Defining and stating goals (activate working memory), "STOP!"-STATE goal	Complex task I Complex task II	*4. Memory II:* Memory and the brain, How memory breaks down, Functional implications of memory loss	Memory challenges
	Home-work	Practice Daily STOP and present mindedness 2. Do the Body scan task. Practice daily present-mindedness 3		Reading assignment memory. Do Brain puzzles.	
3	Morning session	*5. Making decisions:* Competing goals, Emotional reaction to competing goals, To-Do Lists in the "STOP"-STATE	Complex task with "STOP!" Present-mindedness task and to-do-list	*5. Executive functioning and attention:* Executive functions, and how they break down, Attention, and how attention breaks down	Problem solving
		6. Splitting tasks into sub-tasks: Defining overwhelming goals that require splitting, Organizing goal hierarchies, "STOP!"-STATE-SPLIT cycle	Splitting tasks into sub-tasks Wedding task	*6. Lifestyle and neuroplasticity I:* Influence of lifestyle on neuroplasticity and recovery, Stress and brain function, Sleep and brain function	Sleep quality assessment
	Afternoon session	*7. Emotional regulation:* The relationship between thoughts, situations and emotions (the ABC model), Automatic thoughts and present-mindedness, Managing emotional situations	How do thoughts and actions influence feelings? Clapping task with negative feedback from trainer	*7. Lifestyle and neuroplasticity II:* Fatigue, Nutrition and brain function, Physical exercise and brain function	
	Home-work	Log STOP-STATE-SPLIT scenarios. Practice daily present-mindedness task 3. Do the Catalogue Tasks I and II. Log automatic thoughts, situation and feelings		Reading assignment executive functions and attention, sleep, stress, physical training and nutrition. Do the Problem-solving tasks. Log sleep, and practice exercises for good sleep hygiene.	
4	Morning session	*8. Check (STOP!):* Recognizing errors in "STOP!"-STATE-SPLIT cycle, Using "STOP!" to monitor output. Summary of the intervention	Clapping task with "STOP!" by participants	*8. Review.* Summary of the intervention	Brain jeopardy

Table 2. Oblimin rotated factor loadings for Emotional regulation (factor 1), Cognitive executive functioning (factor 2), and Psychological distress (factor 3).

Measure	Factor 1	Factor 2	Factor 3
DEX inhibition	.958		
BRIEF-A self-monitor	.895		
DEX positive affect	.83		
BREQ total	.802		
BRIEF-A emotional control	.748		
BRIEF-A inhibit	.745		
DEX executive memory	.53		
BRIEF-A plan and organize		.939	
BRIEF initiate		.79	
BRIEF-A task monitor		.781	
BRIEF-A working memory		.716	
DEX intentionality		.655	
BRIEF-A organization of materials		.493	
BRIEF-A shift		.474	
HSCL-25 anxiety			.778
HSCL-25 depression			.686

Note. Loadings are presented if >.45. DEX = The Dysexecutive Questionnaire; BRIEF-A = The Behavior Rating Inventory of Executive Function - Adult version; BREQ = The Brain Injury Rehabilitation Trust Regulation of Emotions Questionnaire; HSCL-25 = The Hopkins Symptom Checklist.

Table 3. Nonspecific predictors and moderators of Cognitive executive complaints, Emotional dysregulation, and Psychological distress at six month follow-up

	Cognitive executive complaints					Emotional dysregulation					Psychological distress				
Domain/ Variable	Main effect variable	η^2	Interaction Effect Variable x Treatment	η^2	Status	Main effect variable	η^2	Interaction Effect Variable x Treatment	η^2	Status	Main effect variable	η^2	Interaction Effect Variable x Treatment	η^2	Status
Background and Demographic measures															
Age	$F_{1,65}$=1.21	.019	$F_{1,65}$=.21	.003		$F_{1,65}$=3.96	.061	$F_{1,65}$=.68	.011		$F_{1,66}$=4.77*	.071	$F_{1,66}$=.19	.003	NSP
Sex	$F_{1,65}$=2.01	.032	$F_{1,65}$=1.99	.032		$F_{1,65}$=.37	.006	$F_{1,65}$=.34	.005		$F_{1,66}$=.37	.006	$F_{1,66}$=.09	.001	
Time since injury	$F_{1,65}$=.02	.000	$F_{1,65}$=.51	.008		$F_{1,65}$=.02	.000	$F_{1,65}$=.0	.000		$F_{1,66}$=1.28	.02	$F_{1,66}$=.0	.000	
ABI type															
TBI/other	$F_{1,65}$=.02	.000	$F_{1,65}$=.03	.001		$F_{1,65}$=.09	.014	$F_{1,65}$=.07	.001		$F_{1,66}$=.28	.005	$F_{1,66}$=1.65	.026	
ABI localization															
Frontal/other	$F_{1,59}$=.091	.002	$F_{1,59}$=.02	.000		$F_{1,59}$=0.1	.000	$F_{1,65}$=.0	.000		$F_{1,60}$=.47	.008	$F_{1,60}$=.05	.001	
IQ WASI	$F_{1,65}$=8.72**	.118	$F_{1,65}$=.01	.000	NSP	$F_{1,65}$=.013	.000	$F_{1,63}$=.00	.000		$F_{1,66}$=.63	.01	$F_{1,66}$=1.0	.016	
Neuropsychological measures at baseline															
Attention, Inhibition															
Commissions CPT-II	$F_{1,62}$=.45	.008	$F_{1,62}$=.0	.000		$F_{1,63}$=1.68	.028	$F_{1,63}$=.5	.008		$F_{1,64}$=.25	.004	$F_{1,64}$=.03	.001	
CWIT3	$F_{1,62}$=.01	.000	$F_{1,62}$=.1	.002		$F_{1,63}$=1.65	.027	$F_{1,63}$=3.31	.053		$F_{1,64}$=1.83	.03	$F_{1,64}$=.29	.005	
Attention, Sustained															
Omissions CPT-II	$F_{1,63}$=1.14	.019	$F_{1,63}$=1.3	.021		$F_{1,63}$=.13	.002	$F_{1,63}$=.01	.000		$F_{1,64}$=.31	.005	$F_{1,64}$=.69	.011	
Attention, Shifting															
CWIT4	$F_{1,63}$=.35	.006	$F_{1,63}$=1.09	.018		$F_{1,63}$=.38	.006	$F_{1,63}$=.08	.001		$F_{1,64}$=2.37	.038	$F_{1,64}$=1.13	.019	
Working Memory															
Numbers backwards	$F_{1,65}$=.0	.000	$F_{1,65}$=.68	.011		$F_{1,65}$=.65	.011	$F_{1,65}$=.34	.006		$F_{1,66}$=.64	.01	$F_{1,66}$=.29	.005	
Memory															
Verbal recall	$F_{1,65}$=5.01*	.076	$F_{1,65}$=4.45*	.068	MOD	$F_{1,65}$=3.0	.035	$F_{1,65}$=2.19	.035		$F_{1,66}$=5.31*	.079	$F_{1,66}$=3.41	.052	NSP
Executive function															
Tower total achievement score	$F_{1,65}$=.69	.011	$F_{1,65}$=.3	.005		$F_{1,65}$=.02	.000	$F_{1,65}$=.81	.013		$F_{1,66}$=1.16	.018	$F_{1,66}$=.05	.001	
Tower total moves	$F_{1,65}$=1.72	.027	$F_{1,65}$=5.55*	.083	MOD	$F_{1,65}$=4.4*	.067	$F_{1,65}$=3.18	.05	NSP	$F_{1,66}$=7.33**	.106	$F_{1,66}$=.76	.012	NSP
Self-report at baseline															
Cognition															
CFQ	$F_{1,63}$=17.77***	.231	$F_{1,63}$=.05	.001	NSP	$F_{1,63}$=18.85***	.242	$F_{1,63}$=.09	.002	NSP	$F_{1,64}$=14.87***	.199	$F_{1,64}$=.35	.006	NSP
Executive functioning															
BRIEF-A	NA					NA					$F_{1,65}$=18.67***	.234	$F_{1,65}$=.36	.006	NSP
DEX	NA					NA					$F_{1,65}$=44.45***	.422	$F_{1,65}$=.0	.000	NSP
Emotional regulation															
BREQ	$F_{1,64}$=7.02*	.105	$F_{1,64}$=.8	.013	NSP	NA					$F_{1,65}$=30.87***	.336	$F_{1,65}$=.37	.006	NSP
Psychological distress															
HSCL-25	$F_{1,64}$=14.64**	.196	$F_{1,64}$=2.19	.035	NSP	$F_{1,64}$=13.24**	.181	$F_{1,64}$=.03	.001	NSP	NA				

Note. NSP = Nonspecific predictor; MOD = Moderator; NA = Not applicable; CPT-II = Conners' Continuous Performance Test; CWIT3 = Color Word Interference Test, subtest 3; CWIT4 = Color Word Interference Test, subtest 4; CFQ = Cognitive Failures Questionnaire; BRIEF-A = Behavior Rating Inventory of Executive Function - Adult version; DEX = Dysexecutive Questionnaire; BREQ = The Brain Injury Rehabilitation Trust Regulation of Emotions Questionnaire; HSCL-25 = Hopkins Symptom Checklist. *$p < .05$; **$p < .01$; *** $p < .001$. *N*'s are provided as data were missing for certain measurements.

Table 4. Nonspecific predictors and mediators of Cognitive executive complaints, Emotional dysregulation, and Psychological distress at six month follow-up.

	Cognitive executive complaints					Emotional dysregulation					Psychological distress				
Domain/ Variable	Main effect variable	η²	Interaction Effect Variable x Treatment	η²	Status	Main effect variable	η²	Interaction Effect Variable x Treatment	η²	Status	Main effect variable	η²	Interaction Effect Variable x Treatment	η²	Status
Neuropsychological measures post treatment															
Attention, Inhibition															
Commissions CPT-II	$F_{1,63}$=.44	.007	$F_{1,63}$=1.83	.03		$F_{1,64}$=.0	.000	$F_{1,64}$=.09	.002		$F_{1,64}$=.04	.001	$F_{1,64}$=3.76	.059	
CWIT3	$F_{1,62}$=1.66	.028	$F_{1,62}$=2.24	.037		$F_{1,63}$=1.4	.024	$F_{1,63}$=.33	.006		$F_{1,63}$=3.81	.061	$F_{1,63}$=4.09*	.065	MED
Attention, Sustained															
Omissions CPT-II	$F_{1,65}$=.0	.000	$F_{1,63}$=.28	.005		$F_{1,64}$=.98	.016	$F_{1,64}$=.65	.011		$F_{1,62}$=1.22	.021	$F_{1,62}$=1.68	.028	
Attention, Shifting															
CWIT4	$F_{1,61}$=.84	.015	$F_{1,61}$=.0	.000		$F_{1,61}$=.26	.005	$F_{1,61}$=.01	.000		$F_{1,64}$=.8	.013	$F_{1,64}$=.25	.004	
Executive function															
Tower total achievement score	$F_{1,63}$=.37	.006	$F_{1,63}$=5.04*	.079	MED	$F_{1,64}$=.61	.01	$F_{1,64}$=12.26**	.172	MED	$F_{1,64}$=1.83	.03	$F_{1,64}$=2.93	.047	
Tower total moves	$F_{1,63}$=.06	.001	$F_{1,63}$=1.34	.022		$F_{1,64}$=3.07	.049	$F_{1,64}$=.00	.000		$F_{1,64}$=7.22**	.107	$F_{1,64}$=3.1	.049	MED
Self-report post treatment															
Cognition															
CFQ	$F_{1,63}$=37.04***	.386	$F_{1,63}$=.38	.006	MED	$F_{1,63}$=35.6***	.642	$F_{1,63}$=1.36	.023	MED	$F_{1,64}$=27.81***	.317	$F_{1,64}$=4.16*	.065	MED
Executive functioning															
BRIEF-A	NA					NA					$F_{1,64}$=25.58***	.299	$F_{1,64}$=2.71	.043	MED
DEX	NA					NA					$F_{1,62}$=18.71***	.244	$F_{1,62}$=7.57**	.115	MED
Emotional regulation															
BREQ	$F_{1,63}$=17.37***	.227	$F_{1,63}$=.2	.003	MED	NA					$F_{1,64}$=23.55***	.335	$F_{1,64}$=1.32	.022	MED
Psychological distress															
HSCL-25	$F_{1,63}$=21.75***	.269	$F_{1,63}$=.4	.007	MED	$F_{1,63}$=20.56***	.258	$F_{1,63}$=14.33***	.195	MED	NA				

Note. NSP = Nonspecific predictor; MED = Mediator; NA = Not applicable; CPT-II = Conners' Continuous Performance Test; CWIT3 = Color Word Interference Test, subtest 3; CWIT4 = Color Word Interference Test, subtest 4; CFQ = Cognitive Failures Questionnaire; BRIEF-A = Behavior Rating Inventory of Executive Function Adult version; DEX = Dysexecutive Questionnaire; BREQ = The Brain Injury Rehabilitation Trust Regulation of Emotions Questionnaire; HSCL-25 = Hopkins Symptom Checklist. *p < .05; **p < .01; ***p < .001. *N*'s are provided as data were missing for certain measurements.

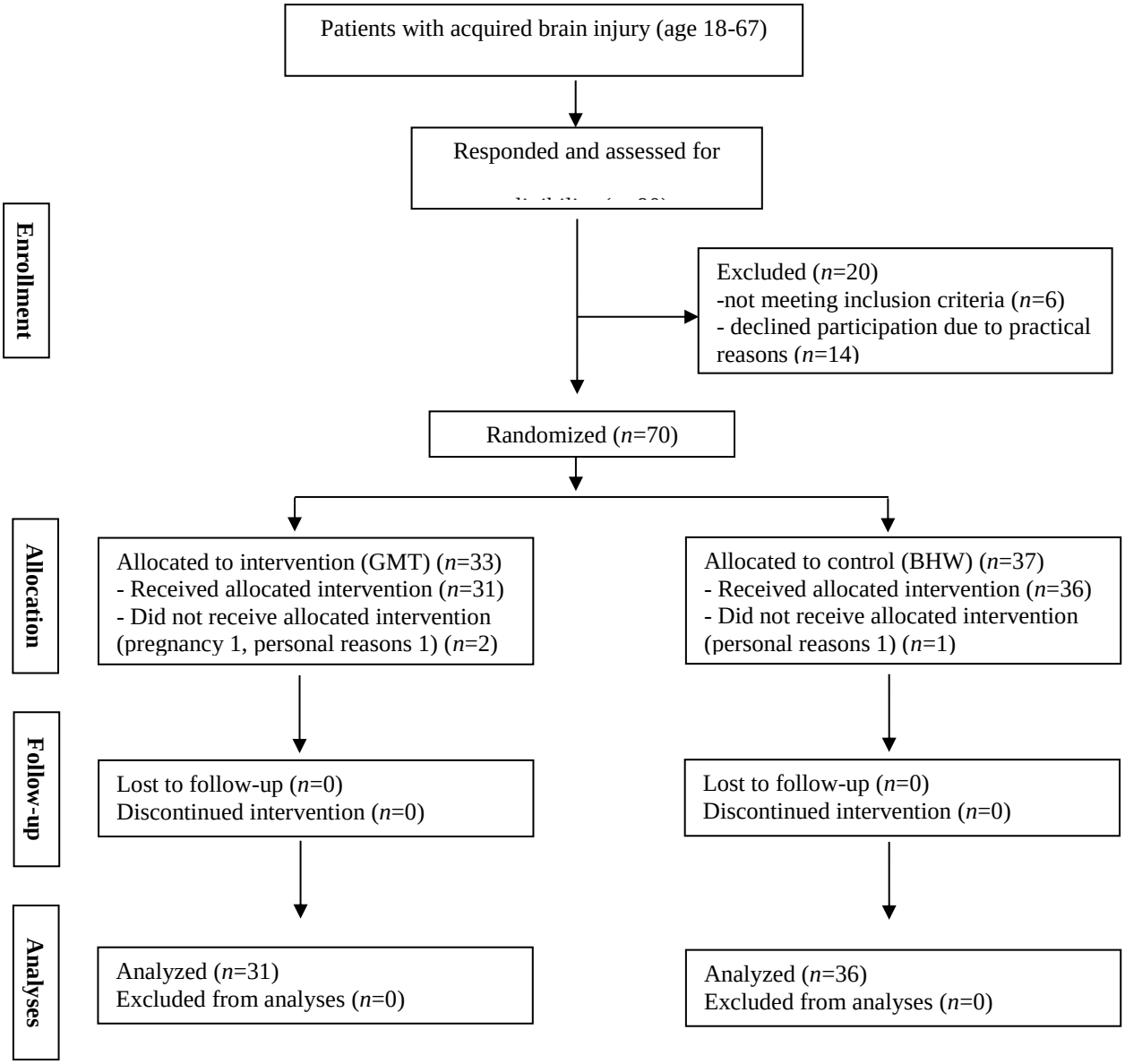

Figure 1. Consort diagram